receivers thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this rule and has concluded that it does constitute a significant regulatory action under the Executive Order.

Regulatory Flexibility Act

The Secretary hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule freezes for 6 months the copayments that certain veterans are required to pay for prescription drugs furnished by VA. The rule affects individuals and has no impact on any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program number and title for the rule are as follows: 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, approved this document on March 12, 2010, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—Veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Dated: June 3, 2010.

William F. Russo,
Director of Regulations Management, Office of the General Counsel.

PART 17—MEDICAL

Accordingly, the interim final rule amending 38 CFR 17.110, which was published at 74 FR 69283 on December 31, 2009, is adopted as a final rule without change.

[FR Doc. 2010–13872 Filed 6–8–10; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AN65

Copayments for Medications After June 30, 2010

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) medical regulations concerning the copayment required for certain medications. Under current regulations, the copayment amount must be increased based on the prescription drug component of the Medical Consumer Price Index (CPI–P), and the maximum annual copayment amount must be increased when the copayment is increased. Under the amendments in this rule, until January 1, 2012, we will freeze copayments at the current rate for veterans in VA’s health care system enrollment priority categories 2 through 6 and increase copayments as required by the current regulation only for veterans in priority categories 7 and 8. Thereafter, if VA does not prescribe a new methodology for increasing copayments, we will resume increasing copayments in accordance with any change in the CPI–P.

DATES: Effective Date: This rule is effective on July 1, 2010.

ADDRESSES: Written comments may be submitted by e-mail through http://www.regulations.gov: by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue, NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to “RIN 2900–AN65—Copayments for Medications After June 30, 2010.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Roscoe Butler, Acting Director, Business Policy, Chief Business Office, 810 Vermont Avenue, Washington, DC 20420, 202–461–1586. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 1722A(a), VA must require veterans to pay a $2 copayment for each 30-day supply of medication furnished on an outpatient basis for the treatment of a nonservice-connected disability or condition. Under 38 U.S.C. 1722A(b), VA “may,” by regulation, increase that copayment and establish a maximum annual copayment (a “cap”). We interpret section 1722A(b) to mean that VA has discretion to determine the appropriate copayment amount and annual cap amount for medication furnished on an outpatient basis for covered treatment, provided that any decision by VA to increase the copayment amount or annual cap amount is the subject of a rulemaking proceeding. We have implemented this statute in 38 CFR 17.110. Under current 38 CFR 17.110(b)(1), veterans are “obligated to pay VA a copayment for each 30-day or less supply of medication provided by VA on an outpatient basis (other than medication administered during treatment).” The regulation ties any increase in that copayment amount to the CPI–P. The current regulation includes an escalator provision for the copayment amount. The regulation states that the copayment amount is established using the CPI–P as follows: For each calendar year or other period as determined by the Secretary of Veterans Affairs beginning after June 30, 2010, the Index as of the previous September 30 will be divided by the Index as of September 30, 2001. The
ratio so obtained will be multiplied by the original copayment amount of $7. The copayment amount for the new year will be this result, rounded down to the whole dollar amount.

Currently, § 17.110(b)(2), also includes a “cap” on the total amount of copayments in a calendar year for a veteran enrolled in one of VA’s health care enrollment system priority categories 2 through 6. There is no cap for a veteran enrolled in priority categories 7 or 8. The amount of the cap was $840 for the year 2002. The current regulation also requires that “[i]f the copayment amount increases * * * the cap of $840 shall be increased by $120 for each $1 increase in the copayment amount.” See 38 CFR 17.110(b)(2).

In January 2006, based on current § 17.110(b), the copayment amount increased to $8 and the cap for priority categories 2 through 6 increased to $960. VA published a notice regarding this change in the Federal Register at 70 FR 72329 (December 2, 2005). Then, on December 31, 2009, VA issued an interim final rule amending § 17.110 to “freeze” until June 30, 2010, the copayment amount at $8 for all veterans. 74 FR 69283 (December 31, 2009). Thereafter, under the regulation, the escalator provision described above would take effect. In a separate document that published today in the rules section (RIN 2900–AN50), we addressed the comments we received concerning the interim final rule and affirmed the interim final rule as a final rule without change. This rulemaking concept was begun on July 1, 2010, after the end of the freeze implemented by the December 31, 2009, rulemaking. It revises the language of § 17.110(b), effective July 1, 2010.

Based on our analysis of the average rate of growth of the CPI–P, the current regulatory methodology, calculated according to the CPI–P methodology, calculated according to the CPI–P as of September 30, 2009, automatically increased the copayment amount from $8 to $9 effective January 1, 2010. Currently, § 17.110(b) does not afford the Secretary of Veterans Affairs discretion to alter the copayment amount as calculated by the CPI–P formula. In a notice announcing the interim final rule, published on December 31, 2009, we stated that we had concerns about an imminent increase in copayments under the methodology in current 38 CFR 17.110(b). 74 FR 69283. We stated that we needed “time to determine whether an increase [in copayments] might pose a significant financial hardship for certain veterans and if so, what alternative would provide appropriate relief for these veterans,” and therefore issued an interim final rule intended “to temporarily freeze copayments and the copayment cap, following which copayments and the copayment cap would increase as prescribed in § 17.110(b).” Thus, although the appropriate copayment amount, under the regulatory formula, increased to $9, we suspended the effect of that increase through June 30, 2010.

Although we continue to believe that the CPI–P is a relevant indicator of the costs of prescriptions nationwide, we need additional time to ascertain whether there might be better indicators upon which we can base our copayment amounts to ensure certain veterans with greater need for medical care and lower income do not face significant financial hardships. In light of this anticipated review and given the current economic climate, we propose to delay implementation of the $1 increase in the copayment amount (and the corresponding $120 increase in the cap) until the completion of our review for veterans in priority categories 2 through 6 of VA’s health care system. See 38 CFR 17.36. We believe that it is appropriate to maintain the current copayment amount for these groups while we review our overall copayment methodology because these groups would be impacted more by the increase in the copayment due to their likely greater need for medical care due to their disabilities or conditions of service. Therefore, we will continue the copayment amount at the current $8 rate for veterans in priority categories 2 through 6 through December 31, 2011, in order to review a number of indicators to base our copayment amounts. The cap will also remain at the current level ($960) for these veterans. Depending on the results of the review described above, the Secretary may initiate a new rulemaking on this subject rather than continue to rely on the CPI–P escalator provision to determine the copayment amount.

At the end of calendar year 2011, unless additional rulemaking is initiated, VA will once again utilize the CPI–P methodology in § 17.110(b)(1) to determine whether to increase copayments and calculate any mandated increase in the copayment amount for veterans in priority categories 2 through 6. At that time, the CPI–P as of September 30, 2011, will be divided by the index as of September 30, 2001, which was 304.8. The ratio will then be multiplied by the original copayment amount of $7. The copayment amount of the new calendar year will be rounded down to the whole dollar amount. As mandated by current § 17.110(b)(2), the annual cap will be calculated by increasing the cap by $120 for each $1 increase in the copayment amount. Any change in the copayment amount and cap, along with the associated calculations explaining the basis for the increase, will be published in a Federal Register notice. Thus, the intended effect of this rule is to temporarily prevent increases in copayment amounts and the copayment cap for veterans in priority categories 2 through 6, following which copayments and the copayment caps will increase as prescribed in current § 17.110(b).

At the same time, in light of our statutory responsibility to control the costs under 38 U.S.C. 1722A and the distinctions noted above regarding veterans in priority categories 2 through 6, we will allow the copayment increase to $9 for veterans in priority categories 7 and 8. See 66 FR 63449 (discussing “the statutory intent * * * for VA to increase the copayment amount” consistent with industry standards). Consequently, we will not further delay the increase to the copayment amount to $9 for priority categories 7 and 8.

Consistent with the requirement of the CPI–P methodology and study of private health care industry standards described above, we will maintain copayments for priority categories 7 and 8 at the $9 rate through December 31, 2011, following which copayments will be increased according to the methodology in proposed § 17.110(b)(1).

We note that we have not yet proposed a new methodology to establish copayments and, for that reason, request public comment only on the aspect of this rulemaking which is to freeze the copayment amount for veterans in priority categories 2 through 6 while we study alternative methodologies to calculate appropriate copayment amounts for all veterans.

Administrative Procedure Act

In accordance with 5 U.S.C. 553(b)(3)(B) and (d)(3), the Secretary of Veterans Affairs finds that there is good cause to dispense with the opportunity for advance notice and opportunity for public comment and good cause to publish this rule with an immediate effective date. As stated above, this rule freezes at current rates the prescription drug copayment that VA charges certain veterans. The Secretary finds that it is impracticable and contrary to the public interest to delay this rule for the purpose of soliciting advance public comment or to have a delayed effective date. Increasing the copayment amount on July 1, 2010, might cause a significant financial hardship for some veterans.

For the above reasons, the Secretary issues this rule as an interim final rule.
VA will consider and address comments that are received within 60 days of the date this interim final rule is published in the Federal Register.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any given year. This rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Executive Order classifies a regulatory action as a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB) unless OMB waives such review, if it is a regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this rule have been examined and it has been determined to be a significant regulatory action under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that this rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule will temporarily freeze the copayments that certain veterans are required to pay for prescription drugs furnished by VA. The rule affects individuals and has no impact on any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program number and title for this rule are as follows: 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, approved this document on March 12, 2010, for publication.

List of Subjects in 38 CFR Part 17

Adминистative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—Veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Dated: June 3, 2010.

William F. Russo,
Director of Regulations Management, Office of the General Counsel.

For the reasons set forth in the preamble, VA amends 38 CFR part 17 as follows:

PART 17—MEDICAL

§ 17.110 Copayments for medication.

(b) Copayments. (1) Copayment amount. Unless exempted under paragraph (c) of this section, a veteran is obligated to pay VA a copayment for each 30-day or less supply of prescription medication provided by VA on an outpatient basis (other than medication administered during treatment).

(i) For the period from January 1, 2010, through June 30, 2010, the copayment amount is $8.

(ii) For the period from July 1, 2010, through December 31, 2011, the copayment amount for veterans in priority categories 2 through 6 of VA’s health care system (see § 17.36) is $8.

(iii) For veterans in priority categories 7 and 8 of VA’s health care system (see § 17.36), the copayment amount from July 1, 2010, through December 31, 2011, is $9.

(iv) The copayment amount for all affected veterans for each calendar year after December 31, 2011, will be established by using the prescription drug component of the Medical Consumer Price Index as follows: For each calendar year, the Index as of the previous September 30 will be divided by the Index as of September 30, 2001 which was 304.8. The ratio so obtained will be multiplied by the original copayment amount of $7. The copayment amount for the new calendar year will be this result, rounded down to the whole dollar amount.

Note to Paragraph (b)(1)(iv): Example for determining copayment amount: The ratio of the prescription drug component of the Medical Consumer Price Index for September 30, 2005, to the corresponding Index for September 30, 2001 (304.8) was 1.1542. This ratio, when multiplied by the original copayment amount of $7 equals $8.08, and the copayment amount in calendar year 2006, rounded down to the whole dollar amount, was set at $8.

3. In § 17.110, amend paragraph (b)(2) by removing “June 30, 2010” in both
I. Background

II. This Action

III. Statutory and Executive Order Reviews

   A. Notice and Comment Under the Administrative Procedures Act (APA)
   B. Executive Order 12866: Regulatory Planning and Review
   C. Paperwork Reduction Act
   D. Regulatory Flexibility Act
   E. Unfunded Mandates Reform Act
   F. Executive Order 13132 (Federalism)
   G. Executive Order 13175
   H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
   I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
   J. National Technology Transfer and Advancement Act

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

L. Congressional Review Act

M. Judicial Review

I. Background

On October 17, 2006, EPA published a final rule revising the 24-hour standard for fine particulate matter (PM_{2.5}) from 65 micrograms per cubic meter (μg/m^3) to 35 μg/m^3. Section 110(a)(1) of the CAA requires states to submit revised SIPs that provide for the implementation, maintenance, and enforcement of a new or revised standard within 3 years after the promulgation of such standard. This finding addresses the first two elements which states must address. This findings notice addresses the first two elements which require each state to submit SIPs which contain adequate provisions to prohibit air pollution within the state that (1) contributes significantly to another state’s nonattainment of the NAAQS; or (2) interferes with another state’s maintenance of the NAAQS. Section 110(a)(1) imposes the obligation upon states to make a SIP submission for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS necessarily affect the content of the submission.

States were required to have submitted complete SIPs that addressed